

September 15, 2000

MEMORANDUM

SUBJECT: **MALATHION:** Revised Chronic Dietary Risk Assessment.

Chemical No.	057701
Reregistration Case	0248
DP Barcode	D267918

FROM: Richard Griffin
Reregistration Branch II
Health Effects Division

THROUGH: Alan Nielsen, Branch Senior Scientist
Reregistration Branch II
Health Effects Division

TO: Paula Deschamp, Risk Assessor
Reregistration Branch II
Health Effects Division (7509C)

Chronic dietary risk assessment for malathion has been revised to reflect both a revision of malathion usage (percent crop treated) estimates and an update of residue data from the Pesticide Data Program (PDP) and the Food and Drug Administration (FDA). For this revised assessment, the PDP data set has been updated by one year (1998) and the FDA data set has been updated by two years (1997/98). Also, due to a lower confidence in overall data quality, FDA "FOODCONTAM" monitoring data has not been used in this updated assessment to derive "anticipated" residue estimates.

Revised chronic dietary risk estimates for the total U.S. population, or any population sub-groups including infants and children, are less than two percent of the malathion chronic Population Adjusted Dose (cPAD) based on exposure estimates for all sites supported for reregistration. For the estimated most highly exposed population subgroup (children 1-6 years old) the two sites estimated to contribute most to chronic exposure are field corn (17% of total exposure) and wheat (45% of total exposure).

Risk assessment for acute dietary exposure to malathion, addressed in the HED risk assessments dated 11/3/99 and 4/27/2000, is not revised in this assessment. A revision is not considered warranted since it was previously determined that acute exposure, even if based on the upper-end assumptions of tolerance level residues and 100% crop treatment, would not exceed the acute Population Adjusted Dose (aPAD) at the 99.9th exposure level.

- ▶ Risk assessment for malathion is based on considerations for parent compound malathion and the oxygen analog metabolite, malaoxon. Malaoxon is accounted for by the use of $\frac{1}{2}$ the limit of quantitation (LOQ) instead of the more typically used $\frac{1}{2}$ the limit of detection (LOD) when calculating anticipated residues (the LOQ is generally 3 times higher than the LOD). A more detailed summary of residues of concern and the calculation of residue estimates for risk assessment can be found in the W. Smith memo to P. Deschamp, dated 5/10/99.
- ▶ The chronic Population Adjusted Dose for malathion is 0.024 mg/kg body weight/day.
- ▶ Chronic exposure estimates for malathion are based, in part, on the revised estimates of (average) usage in the updated *Quantitative Usage Analysis for Malathion* (T. Kiely, 7/19/2000).
- ▶ Malathion is registered for use on more than 100 agricultural crops. Of the total sites considered by the *Quantitative Usage Analysis for Malathion*, 20 sites lacked adequate data for estimating average yearly use. In accord with current HED policy for risk assessment, malathion is assumed to be used on 100% of the total acres of these sites. This assumption would tend to overestimate overall dietary exposure.
- ▶ Chronic exposure attributable to 13 of the total sites is based on their current tolerance level of 8 ppm. Monitoring data is not available for these sites nor is residue data available for the estimation of "anticipated residues". This use of tolerance level residue would tend to overestimate overall dietary exposure.
- ▶ Since the Pesticide Data Program was designed specifically to support risk assessment, with particular emphasis on children's consumption, PDP data is preferred over other data sources (including FDA monitoring data and field trial data). 1994-1998 PDP monitoring data has been used to estimate anticipated residues for 23 of the total sites treated with malathion, and includes the foods of highest consumption, including samples of the two commodities estimated by the DEEM program as the greatest contributors to exposure in children (corn and wheat).

- ▶ Due to a higher confidence, PDP data for oranges/orange juice has been translated to other citrus uses in preference to FDA data (of the citrus group, PDP only samples oranges and orange juice). The variance in size, weight, and composition between citrus types has been accounted for. However, FDA data has been used to estimate residues in citrus peel since PDP samples are peeled prior to analysis.
- ▶ Although residue estimates for the commodities of highest consumption are based on PDP data (or a translation of PDP data, as in the case of citrus), the residue estimates for most commodities are based on other data sources. These include 1992-1998 FDA surveillance data, a translation of FDA data to other commodities, (averaged) field trial data, a translation of field trial data to other commodities, or in a few cases a tolerance of 8 ppm. A summary of commodities, residue estimates, and data sources is attached.
- ▶ Chronic exposure and risk estimates for the total U.S. population and population subgroups is attached.

cc: RF, R. Griffin, W. Smith

Attachment 1. Exposure / Risk Summary

Attachment 2. Residue / Data Source Summary by Crop Group

Attachment 3. Residue / Data Source Summary - Alphabetical Listing

Attachment 1. DEEM Output File

DEEM Chronic analysis for MALATHION (1989-92 data)

Reference dose (RfD, Chronic) = .024 mg/kg bw/day

Total exposure by population subgroup

Population Subgroup	Total Exposure	
	mg/kg body wt/day	Percent of Rfd
U. S. Population (total)	0.000191	0.8%
U. S. Population (spring season)	0.000197	0.8%
U. S. Population (summer season)	0.000184	0.8%
U. S. Population (autumn season)	0.000201	0.8%
U. S. Population (winter season)	0.000181	0.8%
Northeast region	0.000192	0.8%
Midwest region	0.000174	0.7%
Southern region	0.000183	0.8%
Western region	0.000221	0.9%
Hispanics	0.000189	0.8%
Non-hispanic whites	0.000193	0.8%
Non-hispanic blacks	0.000170	0.7%
Non-hisp/non-white/non-black	0.000234	1.0%
All infants (< 1 year)	0.000130	0.5%
Nursing infants	0.000060	0.2%
Non-nursing infants	0.000160	0.7%
Children 1-6 yrs	0.000380	1.6%
Children 7-12 yrs	0.000272	1.1%
Females 13-19 (not preg or nursing)	0.000172	0.7%
Females 20+ (not preg or nursing)	0.000144	0.6%
Females 13-50 yrs	0.000149	0.6%
Females 13+ (preg/not nursing)	0.000132	0.5%
Females 13+ (nursing)	0.000176	0.7%
Males 13-19 yrs	0.000170	0.7%
Males 20+ yrs	0.000173	0.7%
Seniors 55+	0.000150	0.6%
Pacific Region	0.000230	1.0%

			14- Boiled	0. 000400	1. 000
			31- Canned: NFS	0. 000300	1. 000
			32- Canned: Cooked	0. 000300	1. 000
			34- Canned: Boiled	0. 000300	1. 000
			42- Frozen: Cooked	0. 000400	1. 000
			44- Frozen: Boiled	0. 000400	1. 000
150	9B	Squash- summer		0. 000300	1. 000
415	9B	Squash- spaghetti		0. 000300	1. 000
151	9B	Squash- winter		0. 000300	1. 000
17	0	Strawberries		0. 006600	1. 000
416	0	Strawberries- juice		0. 006600	1. 000
103	0	Sugar apples (sweetsop)		0. 500000	1. 000
218	1CD	Sweet potatoes (incl yams)		0. 008700	1. 000
418	2	Sweet potatos-leaves		0. 008700	1. 000
187	4B	Swiss chard		0. 001000	1. 000
Food	Crop			Def Res	Adj. Factor
Code	Grp	Food Name		(ppm)	
37	10	Tangelos		0. 001800	1. 000
38	10	Tangerines		0. 000200	1. 000
39	10	Tangerines- juice		0. 000100	1. 280
420	10	Tangerines- juice-concentrate		0. 001800	3. 200
163	8	Tomatoes- catsup		0. 000100	0. 800
423	8	Tomatoes- dried		0. 000100	14. 300
160	8	Tomatoes- juice		0. 000100	0. 030
162	8	Tomatoes- paste		0. 000100	5. 400
161	8	Tomatoes- puree		0. 000100	0. 600
159	8	Tomatoes- whole		0. 000100	1. 000
219	1AB	Turnips- roots		0. 001000	1. 000
188	2	Turnips- tops		0. 001000	1. 000
431	14	Walnut oil		0. 004500	1. 000
48	14	Walnuts		0. 004500	1. 000
189	0	Watercress		0. 050000	1. 000
147	9A	Watermelon		0. 000100	1. 000
436	9A	Watermelon- juice		0. 000100	1. 000
278	15	Wheat-bran		0. 097700	1. 000
279	15	Wheat-flour		0. 053400	1. 000
277	15	Wheat-germ		0. 097700	1. 000
437	15	Wheat-germ oil		0. 097700	1. 000
276	15	Wheat-rough		0. 097700	1. 000